2009. Subjects had to be continuously enrolled and be >= 18 years of age. Cases had to have at least one incident claim with a primary diagnosis of acute liver necrosis, hepatitis, hepatic coma, hepatorenal syndrome, or coagulopathy. 3:1 controls matched on age, gender, and geographic region were randomly chosen. Acetaminophen maximum and average daily doses were calculated in a range of acute periods (7, 20, and 30 days) and in the chronic one year prior period. Conditional logistic regression was used to estimate the risk of acetaminophen exposure adjusted for comorbidities, other hepatotoxic drugs, and health system factors. **RESULTS:** There were 1350 cases and 4050 controls with a mean age of 47.29 years and 53.85% were male. 116 (8.59%) cases and 144 (3.56%) controls were exposed to acetaminophen in the 30-day prior period with mean maximum daily doses of 3234.32 and 3021.40 mgs. Hepatotoxicity was associated with any acute acetaminophen exposure that decreased with longer look back periods; 7 days (OR=2.23, p<0.001), 30 days (OR=1.84, p<0.001). Cumulative dose in the year prior was not associated with hepatotoxicity (OR=1.05, p=0.889). Acute maximum daily doses >4gms/day were associated with greater risks of hepatotoxicity (OR=2.45, p<0.001). **CONCLUSIONS:** Acute exposure to prescription acquired acetaminophen is associated with increased risk of hepatotoxicity, however use over longer chronic periods was not. Further research is necessary before the safety of chronic acetaminophen can be established.

PGI3

CURRENT TREATMENTS FOR CHRONIC HEPATITIS B: A SYSTEMATIC REVIEW

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OBJECTIVES: The National Institute for Health and Clinical Excellence set the guidance review date for an updated health technology appraisal in the treatment of Chronic Hepatitis B (CHB), including the use of entecavir, as February 2012. The objective of this study was to summarize the published evidence on the clinical efficacy and safety of CHB treatments, through a systematic identification of relevant randomised controlled trials. **METHODS:** A systematic literature search of Embase, Medline, Medline in process and Cochrane CENTRAL databases was conducted based on a research protocol with pre-defined criteria. The search period covered from inception of databases until March 2011. All searches were limited to full publications in the English language pertaining to adults with CHB without HIV co-infection or liver cirrhosis at baseline. The search strategy contains a mixture of free text and index terms. Abstract review and data extraction were performed independently by two members of the project team. The comparators of interest were: Adefovir dipivoxil, Entecavir, Interferon alfa 2a, Interferon alfa 2b, Peginterferon alfa-2a, Peginterferon alfa-2b, Lamivudine, Tenofovir and Telbivudine. Any of the comparisons versus placebo or compared to another drug listed, were included. **RESULTS:** 2,994 articles were identified with 2,107 abstracts reviewed according to the predefined inclusion criteria. A total of 178 full papers were ordered and 27 papers (n=9,033) included in the final analysis. Extensive data was extracted related to key patient population details, interventions used, baseline characteristics, endpoint data at numerous time points (up to 24 months) and adverse events. The methodological quality of trials was assessed using the Cochrane Collaboration's tool for assessing risk of bias. **CONCLUSIONS:** Although the literature base is mature in terms of number of RCTs, due to the number of treatments available the evidence network is weak. From those results, further analysis through a network meta-analysis, adjusting for cross-trial differences between study populations, should be investigated.

PGI4

COST-EFFECTIVENESS OF ESOMEPRAZOLE VERSUS PANTOPRAZOLE IN ACUTE AND MAINTENANCE TREATMENTS OF REFLUX ESOPHAGITIS IN TURKEY

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OBJECTIVES: To assess the cost effectiveness in Turkey of acute treatment of reflux esophagitis (RE) with esomeprazole (ESO) 40mg once daily (od) followed by maintenance treatment with 20mg od versus acute treatment with pantoprazole (PA) 40mg od followed by maintenance treatment with 20mg od. **METHODS:** In the present study, ESO and PA were compared in a decision analytic model in terms of costs and effectiveness. To assess the effectiveness, probabilities for treatment success, which was healing of RE during initial acute treatment or a relapse while on maintenance treatment, were obtained from the randomized, double-blind, multi-center EXPO study. Patients healed after initial four to eight weeks acute treatment received 6 months maintenance treatment. Therefore, all patients were followed for seven months in the model. Direct medical costs were assessed based on the perspective of the health care provider. Association between RE and lost work productivity was regarded as 5.3 hours per employed patient per week. Sensitivity analyses were performed by using upper and lower 95% confidence intervals of the clinical study effectiveness results, as well as by changing patient management assumptions. **RESULTS:** Probability of treatment success per patient in the ESO and PA strategy was 83.4 % and 69.6 %, respectively after 7 months. Mean direct medical costs per patient in the ESO and PA strategy were the same; 152 TL in both strategies. Total costs included direct medical costs and indirect costs, which consisted of work absence and reduced work productivity. Total costs for ESO and PA strategy were 247TL and 274TL, respectively implying a cost-saving of 27TL for ESO. Sensitivity analyses supported stability of main findings for a range of scenarios. **CONCLUSIONS:** When considering total costs from a societal perspective, results indicate that esomeprazole treatment is dominant; esomeprazole provided a better clinical effectiveness at lower costs.

PGI5

IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (IBS-C): A EUROPEAN-FOCUSED SYSTEMATIC LITERATURE REVIEW OF DISEASE BURDEN

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OBJECTIVES: To explore disease burden, economic impact, treatment landscape and unmet medical needs in patients with IBS-C. **METHODS:** We conducted a review of MEDLINE- and EMBASE-indexed and 'grey' literature (citeable material that is often not published in peer-reviewed, indexed medical journals, e.g.,web-based international treatment guidelines) published in the last decade (January 2000 to December 2010) pertaining to the epidemiological, clinical, economic, and humanistic impact of IBS-C with a European country focus (France, Germany, Italy, Spain, UK). **RESULTS:** Altogether 885 unique studies were identified; 106 were included in the analysis. Among patients with IBS, the prevalence estimates of IBS-C range from 24% to 44%. Comorbid conditions such as personality and psychological traits and stress, are common. Patients with IBS-C have lower health-related quality of life (HRQoL) compared with the general population (18 studies); treatment of IBS-C can improve HRQoL. The European societal cost of IBS-C is largely unknown; no European cost-of-illness (COI) studies were identified specifically on IBS-C. In the absence of European data, US data show IBS-C to be cost-intensive. Two cost analyses demonstrated the substantial societal impact of IBS-C, with adult patients experiencing reduced productivity at work or through work absenteeism (mean number of days off work annually: 8.5 to 21.6 days) due to severe, disruptive symptoms. European and local IBS treatment guidelines (where available) offer similar diagnostic/management recommendations; however, IBS-C treatment varies by country. Current monotherapy options for treating IBS-C are suboptimal. 5-HT4 agonists have been evaluated for IBS-C; however, they have been associated with ischaemic colitis or a lack of substantial benefit in IBS-C versus placebo. **CONCLUSIONS:** Our literature search indicates a lack of monotherapy treatment options to adequately manage IBS-C patients, and the need for European focussed burden of disease and COI studies, to address the evidence gaps identified in this systematic literature search.

PGI6

THE DEVELOPMENT AND EXTERNAL VALIDATION OF A MODEL TO PREDICT ONE YEAR ALL-CAUSE MORTALITY FOLLOWING LIVER FUNCTION TESTS IN PRIMARY CARE PATIENTS

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OBJECTIVES: In patients with raised liver function tests (LFTs) but without clinically apparent liver disease, the appropriate level of follow-up to take can be unclear. Our aim was to develop and validate a prediction model to estimate the risk of one year all-cause mortality in patients with LFTs taken in primary care. **METHODS:** A population-based retrospective cohort of patients, without clinically apparent liver disease, in Tayside Scotland was identified as having their first LFTs performed in primary care and followed for one year. Biochemistry data were record-linked to secondary care, prescriptions and mortality data to ascertain baseline characteristics including LFTs, age, gender, deprivation, comorbidities, alcohol and drug dependency, methadone use, and statin, NSAIDs or antibiotic use. Multiple imputation was used to impute missing values for LFTs. Parametric accelerated failure time survival models were fitted to predict all-cause mortality. The final model was assessed for discriminatory ability using the C-statistic. A separate validation cohort was obtained from 19 general practices across Scotland to externally validate the final model. **RESULTS:** Predictors of all-cause mortality model included male gender, age, social deprivation, history of cancer, renal disease, stroke, ischaemic heart disease and respiratory disease, statin use, and all LFTs. A model integrating these predictors had excellent discriminatory ability (C-statistic (95% CI) = 0.82 (0.80, 0.84)) and calibrated well internally. The external validation had a C-statistic of 0.86 (0.79, 0.90) with very good calibration. The model without LFTs had a C-statistic of 0.63 (95% CI 0.61, 0.66). **CONCLUSIONS:** This study has developed and externally validated a model that predicts risk of mortality in patients with no apparent liver disease but tested for LFTs in primary care. This model can be used in practice by general practitioners and others working in community settings to improve management of these patients with the potential to save costs to the health system.

Gastrointestinal Disorders – Cost Studies

PGI7

IMPACT OF COMPLICATIONS FROM DYSPHAGIA ON HOSPITAL CHARGES IN THE UNITED STATES

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OBJECTIVES: Unmanaged dysphagia exposes patients to risk of malnutrition, dehydration, urinary tract infections (UTI) and aspiration pneumonia. It has been demonstrated that dysphagia screening and management may reduce the risk of developing complications and incurring increased hospital charges. The objective of this analysis is to quantify the additional charges associated with common complications of dysphagia. **METHODS:** Using 2008 Health Care Utilization Project (HCUP) data, individuals with a recorded diagnosis of dysphagia (ICD-9 CM: 438.82, 787.2-787.29) were identified. The mean (10% trimmed) hospital charges for indi-

viduals with and without a recorded comorbid diagnosis of malnutrition, dehydration, UTI and aspiration pneumonia were compared. As there was a significant interaction between number of comorbidities and hospital charge in the UTI and pneumonia sample, an analysis of covariance (ANCOVA) model was employed to adjust the UTI and pneumonia analyses for this influence. The model was adjusted for complication diagnosis as a factor and both 1) number of comorbidities, and 2) complication diagnosis and number of comorbidities interaction as covariates. **RESULTS:** The most common complications reported in patients with a recorded diagnosis of dysphagia were UTI (27%, n=3424), pneumonia (26%, n=3348), dehydration (12%, n=1507), and malnutrition (8%, n=1027). Dysphagia patients with complications had significantly higher mean hospital charges than those without the complications UTI ($35,358 vs. $30,373, p<0.001), pneumonia ($33,085 vs. $31,184, p<0.001), dehydration ($28,093 vs. $20,850, p<0.001), and malnutrition ($37,192 vs. $34,747, p<0.001), and MS ($32,406 vs. $23,726, p<0.001). **CONCLUSIONS:** Our results demonstrate that having to treat the complications of dysphagia adds significantly to the cost of hospital care. Proactive management of patients with dysphagia may confer substantial savings to hospitals.

PGI8

COST ANALYSIS AND INCIDENCE OF ADVERSE GASTROINTESTINAL EVENTS FOLLOWING BISPHOSPHONATE TREATMENT AMONG WOMEN WITH OSTEOPOROSIS IN TAIWAN

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OBJECTIVES: To investigate the cost and incidence of adverse gastrointestinal (GI) events caused by bisphosphonate therapy in Taiwan. **METHODS:** We conducted a retrospective cohort study based on the National Health Insurance Research database in Taiwan from 2005 to 2009. The inclusion criteria for the study cases were patients 1) who sought inpatient or outpatient care for gastrointestinal problems with ICD9-CM codes of GI-related diagnosis within 4 months after the initiation of filling bisphosphonate prescription (the index date) for bisphosphonate, and 2) who have no prior history of GI treatment 90 days before the index date. The costs and incidence associated with GI adverse events were assessed based upon survival analysis and generalized linear models. **RESULTS:** A total of 114,086 patients were included in this study. The GI incidence rate was lower in the group treated with risedronate (16%) than alendronate (25%). The average time of onset of GI event was longer after taking risedronate (1.6 months) than taking alendronate (1 month). The average direct medical cost associated with a GI event was $3147(USD) and $6235 (USD) in group treated with risedronate and alendronate, respectively. The distribution of costs of GI events was physician consultation fees (35%), examination fee (10%), drug costs including proton pump inhibitors (22%), H2-blocker (14%), cytoprotectants (7%) and other GI related costs (12%). **CONCLUSIONS:** Bisphosphonate treatment of osteoporosis may involve adverse GI events and their associated medical costs should be taken into account when evaluate cost-effectiveness of treatment for osteoporosis.

PGI9

IMPACT OF DYSPHAGIA ON U.S. HOSPITAL CHARGES IN PATIENTS WITH COMORBID CONDITIONS

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OBJECTIVES: Dysphagia has been previously shown to increase hospital length of stay (LOS) (Altman et al, 2010). The objective of this study was to quantify the difference in hospital charges between patients identified with and without dysphagia among commonly associated neuromuscular, neurologic and cardiovascular diseases. **METHODS:** Using 2008 Health Care Utilization Project (HCUP) data, individuals with a hospital discharge diagnosis of stroke, Alzheimer's disease (AD), ALS, dementia, heart failure (HF), multiple sclerosis, cerebral palsy, Huntington's disease, and Parkinson's disease (PD) were identified using ICD-9 CM diagnosis codes. Within each disease state, the mean (10% trimmed) hospital charges for individuals with a recorded diagnosis of dysphagia (ICD-9: 438.82, 787.2-787.29) were compared to those without dysphagia. An analysis of covariance (ANCOVA) model was employed to account for potential impact of comorbidities on hospital charges. The model was adjusted for dysphagia diagnosis as a factor and both 1) number of comorbidities, and 2) dysphagia diagnosis and number of comorbidities interaction as covariates. **RESULTS:** Dyphasgia was most commonly diagnosed in patients with stroke (41.2%, n=11,736), dementia (0.6%, n=1,126), AD (0.4%, n=489) and HF (0.3%, n=2,087). Cerebral palsy, PD, HD, and ALS were excluded from the analysis due to small dysphagia sample (n<10). Patients with dysphagia demonstrated higher mean hospital charges compared with non-dysphagia patients for stroke ($32,531 vs. $26,004, p<0.001), dementia ($26,836 vs. $23,445, p<0.001), AD ($25,431 vs. $22,915, p<0.001), HF ($30,686 vs. $26,984, p<0.001), and MS ($32,406 vs. $23,726, p<0.001) adjusted for number of comorbidities. The magnitude and direction of the association between dysphagia and hospital charges were consistent in both the bivariate and multivariate analyses. **CONCLUSIONS:** Our results demonstrate that patients with conditions that are complicated by dysphagia cost hospitals significantly more than similar patients without dysphagia and management of these patients can avert significant costs.

PGI10

ANALYSIS OF ORIGINATOR VERSUS GENERIC PRESCRIBING OF PROTON PUMP INHIBITORS

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OBJECTIVES: Generic prescribing is important in South Africa. Many medical aid schemes will only reimburse the cost of the generic product, and a co-payment is required if a patient wants to use the originator product. The primary aim of this study was to investigate originator versus generic prescribing focussing on proton pump inhibitors (PPIs). **METHODS:** Prescription data were obtained from a private medical aid administrator in South Africa. The data covered 2010 and included medication, procedures and devices (a total of 2126264 records). For the purpose of this study, only PPI medicine items were extracted and analysed (MIMS category 12.4.4). Basic descriptive statistics were calculated. **RESULTS:** A total of 20537 PPIs were prescribed (only 18.56% on the chronic option of the medical aid schemes). Five different PPI active ingredients were prescribed to 7060 patients (50.88% female patients). Omeprazole was the most often prescribed PPI, accounting for half of all PPI prescribing (50.78%), followed by esomeprazole (19.83%) and lansoprazole (18.04%). Eight different trade names of omeprazole were prescribed (one generic product accounted for 56.00% of all omeprazole prescriptions and 56.08% of the cost of omeprazole prescriptions). The originator product only accounted for 1.75% of omeprazole prescribing frequency and 3.07% of prescribing cost. Only one trade name of esomeprazole was prescribed (no generic equivalents) and nine trade names of lansoprazole (the originator accounted for 1.43% of prescribing frequency and 2.51% of cost). On average, esomeprazole had the highest average cost of R308.97, followed by rabeprazole (R236.58). Both these products do not have generic equivalents on the South African market. **CONCLUSIONS:** Further studies that include dosage forms and prescribed daily doses (PDDs) should be conducted alongside cost analyses. A clear difference between the prescribing and cost of originator versus generic prescribing was detected in this study.

PGI11

COST ANALYSIS OF ANTIHELICOBACTER THERAPY OF GASTRIC AND DUODENUM ULCER IN UKRAINE

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OBJECTIVES: To determine the cost range for different forms of antyhelicobacter therapy (first and second line) of the working age patients with gastric and duodenum ulcer in Ukraine. **METHODS:** Different variants of (triple and quadrotherapy) of traditional schemes of antihelicobacter therapy, recommended by "Maastriht" (2005) have been used in the research. When treatment course costs determination for antihelicobacter therapy for one patient, the expenses only for drugs included in the tested schemes have been taken. The prices for drugs have been taken from the information system "Medicinal preparations", Morion Company (August 2010). The currency rate to dollar (USA) on August 31, 2010 was 7,89:1. Medicinal preparations with minimal and maximal costs for the disease treatment course have been included for the costs range evaluation for the course of antihelicobacter therapy of the first and second line for one patient. **RESULTS:** The costs range of antihelicobacter therapy of the first and second line in Ukraine is rather large, $ 5,71– $ 238,55 and $ 5,78 – $ 149,26, respectively. It is connected with big difference between the cost of original and generic drugs, included into antihelicobacter therapy scheme. **CONCLUSIONS:** The cost for antihelicobacter gastric ulcer and duodenal therapy course with the use of original and foreign generics can be rather high in Ukraine. In connection with it, when drugs choosing it is reasonable to use pharmacoeconomics research results, that will help to optimize the state, insuaring companies and patients expenses for the disease treatment.

PGI12

GASTROESOPHAGEAL REFLUX DISEASE PATIENTS WHO SWITCHED FROM A BRANDED PROTON PUMP INHIBITOR TO A GENERIC ONE AND VICE VERSA: A COST COMPARISON

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OBJECTIVES: To compare health care costs between patients who switched from a branded proton pump inhibitor (PPI) to a generic PPI and vice versa. **METHODS:** We conducted a retrospective database analysis using commercial enrollees from a large US health plan from February 2008 to March 2010. Continuously eligible adult patients who had gastroesophageal reflux disease (GERD) or GERD-related conditions, and evidence of PPI use during February 2009 to September 2009 were included. The index PPI was defined as the first PPI prescribed during the identification period. The two cohorts in this study included patients who switched from a generic PPI to a branded index PPI versus patients who switched from a branded index PPI to a generic index PPI. Risk adjustment was performed using propensity score matching. We controlled for age, gender, region, GERD severity, plan, pre-index Quan-Charlson comorbidity score (CCI), baseline daily average consumption (DACON), and baseline costs and utilization. **RESULTS:** A total of 9881 patients from each cohort were matched after propensity score matching. During the 6 months after the switch, there were no statistically significant differences between the two cohorts in terms of office visit costs, outpatient costs, emergency services costs, inpatient costs, and other costs., However, patients who switched to a generic PPI had lower pharmacy costs ($1919 vs. $2306, p<0.001). **CONCLUSIONS:** Although pharmacy costs are slightly lower for patients who switched from a branded to a generic PPI, there were no significant differences in other health care costs such as for office visits, emergency room services, and inpatient visits.

PGI13

EVALUATION OF THE CLINICAL AND ECONOMIC BURDEN OF CHRONIC CONSTIPATION IN BELGIUM

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